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MCDERMOTT, WILL & EMERY			SHAW, AMANDA MARIE	
4370 LA JOLLA VILLAGE DRIVE, SUITE 700			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/643,775	LIE ET AL.
	Examiner Amanda M. Shaw	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 4/12/2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-62 is/are pending in the application.
 4a) Of the above claim(s) 1-39, 54 and 55 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 40-53 and 56-62 is/are rejected.
 7) Claim(s) 61 and 62 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 8/18/2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed April 12, 2007. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made non-final.

Claims 1-62 are currently pending. Claims 1-10 and 13-37 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim 1. Claims 50, 59, and 60 have been amended.

It is noted that in the response filed July 5, 2007 the Applicants elected to have SEQ ID Nos 183-188 to be searched. Claims 11-12, 38-39, and 54-55 are either missing SEQ ID Nos or depend on claims which are missing SEQ ID Nos. Based on the number of sequences elected by the applicant it is impossible for the examiner to determine which sequence belongs in each claim. Therefore, claims 11-12, 38-39, and 54-55 are also withdrawn as being drawn to non elected subject matter since the claims do not recite the elected SEQ ID NOs.

Accordingly, Claims 40-53 and 56-62 have been addressed herein.

Specification

2. The following are new objections:

The specification is objected to because Figure 1-11 contain multiple sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Where drawings in a patent application show a sequence that is set forth in the "Sequence Listing" reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the brief description of the figures.

The specification is also objected to because several pages refer to SEQ ID Numbers that are missing (See for example pages 6-10). Applicants are required to fill in the missing SEQ ID Nos. Applicants are also reminded that new matter may not be added to the specification.

Claim Objections

3. The following are new objections:

Claim 61 is objected to because the claim the claim appears to depend from claim 60 however claim 61 is drawn to "the method of claim 42". Appropriate correction is required.

Claim 62 is objected to because the claim recites the phrase "wherein said central database of candidate parent genotypes is on the accessible through the internet". This phrase should recite, "wherein said central database of candidate parent genotypes is accessible through the internet". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-53 and 56-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following are new claim rejections:

Claims 41 and 42 are indefinite over the recitation of the phrase "a method of determining the origin of a fish sample". This phrase is considered indefinite because it is unclear "origin of a fish sample" refers to the "population of origin" or if it refers to the "parentage of origin".

Claim 50 recites the limitation "the extracted nucleic acid". There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to a step of "extracting nucleic acid" it does not refer to "extracted nucleic acid".

Claims 60-62 are indefinite for failing to further limit the subject matter of a previous claim. For example it is unclear how generating a database limits the method of claim 42 which is drawn to determining the origin of a fish sample. Additionally it is unclear if the database that is generated is the same database of claim 42 or a different database.

Claims 61 and 62 recite the limitation "said central database". There is insufficient antecedent basis for this limitation in the claims.

Claims 61 and 62 are rejected over the phrase "wherein said central database is capable of instantaneously comparing said sample genotype to said collection of candidate parent genotypes". Capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear as to whether the central database does compare said sample genotypes to said collection of candidate parent genotypes or if the central database only has this ability under some unspecified conditions.

The following is a previously presented rejection:

Claims 50-58 remain indefinite over the recitation of the phrase "extracting nucleic acid corresponding to distinct populations." Corresponding is not an art recognized term to describe the relationship between a nucleic acid sequence and a population. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid and amino acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Response To Arguments

5. In the response filed April 14, 2007, Applicants requested the removal of the 112 2nd paragraph rejections on the basis that the rejections have been rendered moot by the amendments made to the claims. This argument has been fully considered but is

not persuasive because claim 50 still recites the phrase "extracting nucleic acid corresponding to distinct populations". Once again the term "corresponding" has not been defined by the specification or claims. Additionally it is not clear as to whether a corresponding nucleic acid refers to a nucleic acid sequence is only found in a distinct population or if it refers to similar nucleic acid sequences found in other populations. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid and amino acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Please note that claims 40-41 are being interpreted as a method of determining the population origin of a fish and claims 42-53 and 56-62 are being interpreted as a method of determining the parentage origin of a fish.

The following is a new rejection

7. Claims 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Tessier et al (Animal Genetics 1998).

Tessier et al teach a method wherein the origin of Atlantic salmon (which belong to the family Salmonidae and the species *Salmo salar*) were determined using microsatellites. Tessier et al teach that there are four tributaries run into Lake St Jean. Using seven microsatellite loci and mtDNA, Tessier was interested in determining whether fish spawning in different tributaries form genetically distinct populations. Allele frequency distribution, molecular variance, and genetic distance estimates all supported their hypothesis of genetic differentiation among salmon from different tributaries (Abstract, Page 738). Thus Tessier et al teach that it is possible to determine the population of origin (i.e., which tributary the fish originated from) of Atlantic salmon based on its DNA. In the instant case the information collected on the fish in this study is being interpreted as a database because by definition a database is any collection of stored data.

The following is a previously presented rejection:

8. Claims 42-43, 45-46, 50-52, and 59-60 remain rejected under 35 U.S.C. 102(b) as being anticipated by O'Reilly et al (Animal Genetics 1998) for the reasons set forth in the Office Action of October 12, 2006 and reiterated below.

Regarding Claim 42 O'Reilly et al teach a method wherein parentage of 792 Atlantic salmon were determined using microsatellites. O'Reilly et al teach that twelve mature female and 12 mature male Atlantic salmon were used. Several measures of locus variability and information content were calculated for microsatellite data from the 24 parents in this study. Parentage was determined by comparing alleles at a give

locus from each offspring with alleles from each of the potential parental crosses (Page 363-364). In the instant case the information collected on the parents in this study is being interpreted as a database because by definition a database is any collection of stored data.

Regarding Claim 43 O'Rielly et al teach that twelve mature female and 12 mature male Atlantic salmon were used. Several measures of locus variability and information content were calculated for microsatellite data from the 24 parents in this study. Therefore there was genotype information for every potential parent (Page 364).

Regarding Claims 45 and 46 O'Rielly et al analyzed Atlantic Salmon which belong to the family Salmonidae and the species *Salmo* *salar* (Page 363).

Regarding Claim 50 O'Rielly et al teach a method wherein blood and muscle tissue was taken from the Atlantic Salmon and the DNA was isolated and purified prior to DNA typing. Microsatellite variation was surveyed at one dinucleotide (Ssa85) and three tetranucleotide loci (Ssa171, Ssa197, and Ssa202) (Page 364).

Regarding Claim 51 O'Rielly et al teach that twelve mature female and 12 mature male Atlantic salmon were obtained in November 1989 from a managed broodstock line from the Salmon Genetic Research Program, St Andrews, New Brunswick (Page 364).

Regarding Claim 52 O'Rielly et al teach that the genetic markers being looked at were microsatellites. Microsatellite variation was surveyed at one dinucleotide (Ssa85) and three tetranucleotide loci (Ssa171, Ssa197, and Ssa202) (Page 364).

Regarding Claim 59 O'Rielly et al teach a method wherein the absence of a match excludes said candidate genotypes as the origin of the said sample. Specifically O'Rielly et al teach that samples of offspring that did not match any of the 12 sets of parents were analyzed further to identify the source of the mismatch or incompatibility (Page 365).

Regarding Claim 60 O'Rielly et all collected information on the parent genotypes of the Atlantic salmon (Page 364). In the instant case the information collected on the parents in this study is being interpreted as a database because by definition a database is any collection of stored data.

Response To Arguments

9. In the response filed April 12, 2007, Applicants traversed the rejection over O'Reilly by stating that O'Rielly neither teaches nor suggests candidate parent genotypes representing distinct populations of origin. This argument has been fully considered and is persuasive to overcome the rejections of over claims 40 and 41but is not persuasive to overcome the rejections over claims 42-43, 45-46, 50-52, and 59-60. Specifically claim 42 recites "said candidate parent genotypes represents a distinct origin". Thus the claims do not require that the parent genotypes represent different populations of origin. In the instant case a "distinct origin" could be a "population origin" or "parentage origin". The claims have been given the broadest reasonable interpretation and thus the phrase "said candidate parent genotypes represents a

distinct origin" can be interpreted as candidate parent genotypes which represent a distinct parentage origin.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Please note that claims 40-41 are being interpreted as a method of determining the population origin of a fish and claims 42-53 and 56-62 are being interpreted as a method of determining the parentage origin of a fish.

The following are previously presented rejections:

11. Claims 44 and 47-48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Agresti (Aquaculture 2000) as evidenced by Rico (Proceedings: Biological Sciences) for the reasons set forth in the Office Action of October 12, 2006 and reiterated below.

The teachings of O'Reilly et al are presented above.

Regarding Claims 44 and 47-48 O'Reilly et al do not teach a method wherein the candidate parent genotypes belong to at least two different species and the species is *Oreochromis niloticus* (Nile Tilapia).

However Agresti et al teach a method for deriving genetically superior tilapia produced from inter crossing five different species of fish: *Oreochromis nioticus* (Nile Tilapia), *Oreochromis aureus*, *Oreochromis mossambicus*, and *Sarotherodon galilaeus*. A genomic map has been created for each of the parents using microsatellite and AFLP DNA markers (Abstract). Agresti et al teaches that these markers can be used to track the parentage of crosses between the different species of Tilapia (Page 54).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of O'Reilly et al to determine parentage of tilapia when the candidate parent genotypes belong to more than one species of tilapia as suggested by Agresti et al for the benefit of being able to distinguish between species of tilapia which can not be distinguished based on morphology alone. Further the prior art of Rico (Proceedings: Biological Sciences) et al

teach that they studied the conservation of microsatellites among distantly related species of fish and patterns of cross species polymorphisms. Specifically they used primer pairs from 18 microsatellite loci on a panel of different fish species. Rico et al teach that microsatellites are often hypervariable in number and length and that the flanking nucleotides of the microsatellite regions are also polymorphic. Thus studying microsatellites and the regions which flank microsatellites have become an important source of polymorphic genetic markers for parentage testing (Abstract, page 549, and Table 2).

12. Claim 49 remains rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Garcia de Leon (Aquaculture 1998) for the reasons set forth in the Office Action of October 12, 2006 and reiterated below.

The teachings of O'Reilly et al are presented above.

Regarding Claim 49 O'Reilly et al do not teach a method wherein the sample and candidate parent genotypes belong to a species selected from the group consisting of rainbow trout, halibut, sea bass and Atlantic cod.

However Garcia de Leon et al teach a method in which microsatellite markers are used to determine parentage in sea bass (Abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of O'Reilly et al to sea bass for the benefit of being able to study an additional fish.

13. Claim 53 remains rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Fries (Nature 2001) for the reasons set forth in the Office Action of October 12, 2006 and reiterated below.

The teachings of O'Reilly et al are presented above.

Regarding Claim 53 O'Rielly et al does not teach that the method wherein the genetic markers are SNPs.

However, Fries et al teach a method for verification of identity and parentage using a standardized set of single nucleotide polymorphisms as an alternative to microsatellite analyses (Page 508).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O'Rielly et al by using SNPs as suggested by Fries because SNPs have a low mutation rate, are suitable for standardization, and they do not require a specific typing platform.

14. Claim 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) and Fries et al (Nature 2001) as applied to claim 53 above, and in further of Cox (US Patent 6406847 Filed 1999) for the reasons set forth in the Office Action of October 12, 2006 and reiterated below.

The teachings of O'Reilly et al and Fries et al are presented above.

Regarding Claims 56-58 the combined references do not teach that the method of identifying the SNP is performed using an oligonucleotide ligation assay (OLA) or using a hybridization assay on a DNA chip.

However, Cox et al teach that there are multiple methods such as chip hybridization and oligonucleotide ligation assay (OLA) that have been developed for genotyping SNPs (Column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of O'Reilly and Fries by detecting the SNPs using OLA or chip hybridization as suggested by Cox because both of these procedures were routinely used for genotyping SNPs at the time of the presently claimed invention.

15. Claims 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Dodds (US Patent 6287254 Filed 1999) for the reasons set forth in the Office Action of October 12, 2006 and reiterated below.

The teachings of O'Reilly et al are presented above.

Regarding Claims 61-62 O'Reilly does not teach that the database is capable of instantaneously comparing the sample genotype to the collection of genotypes and that the database is accessible through the Internet.

However, Dodds et al teach a genotype database which stores data which is in the category of mostly genotype or genetic information. The information in the databases is then used to build computer driven statistical models. The computer network may conveniently include the Internet (Column 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O'Reilly et al by storing the information in a computer that is connected to the internet as suggested by Dodds for the benefit of being able to share the information obtained from genotyping locally, regionally, nationally, and globally (Column 3).

Response To Arguments

16. In the response filed April 12, 2007, Applicants traversed the rejection over O'Reilly in view of Agresti, Garcia de Leon, Fries, Cox, and Dodds by stating that primary reference (O'Reilly) neither teaches nor suggests candidate parent genotypes representing distinct populations of origin. The applicants further argue that the secondary references (Agresti, Garcia de Leon, Fries, Cox, and Dodds) do not cure the deficiencies of the primary reference. This argument has been fully considered but is not persuasive to overcome the rejections over claims because claim 42 recites "said candidate parent genotypes represents a distinct origin". Thus the claims do not require that the parent genotypes represent different populations of origin. In the instant case a "distinct origin" could be a "population origin" or "parentage origin". The claims have been given the broadest reasonable interpretation and thus the phrase "said candidate parent genotypes represents a distinct origin" can be interpreted as candidate parent genotypes which represent a distinct parentage origin.

Double Patenting

The following is a new rejection

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-53 and 56-62 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 62-83 of copending Application No. 10349331.

Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the present claims and the claims of '331 encompass methods for determining the population of origin of a sample and the parentage origin of a sample by using a database that contains a collection of genotypes derived from samples. In the methods a sample genotype is compared to the database in order to determine the

population that the sample originated from and to determine the parentage of the sample. Claims 40-41 of the instant application are drawn to determining the population of origin of a fish sample. Claims 42-62 of the instant application are drawn to determining the parentage origin of a fish sample. On the other hand, Claim 62 of the '331 application are drawn to determining both the parentage origin and population origin of any type of sample from any plant and animal species that has reproduction involving the mating of two parents to produce a set of offspring. Both claim sets further limit the animal species to fish and recite various types of fish (i.e. Salmon, tilapia, cod etc.) Thus the present claims as written encompass multiple embodiments, all of which are anticipated by the '331 claims. For example, embodiments of claim 40 for determining the population origin of a fish are anticipated by claim 62 of the '331 application, as the '331 claims set forth all the method steps and structural limitations required by these embodiments of the present claims. For these reasons the conflicting claims are not patentably distinct from each other. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

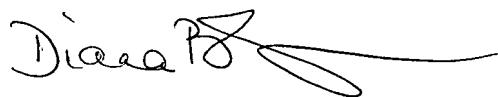
18. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634



DIANA JOHANNSEN
PRIMARY EXAMINER